K062626

SUMMARY OF
SAFETY AND EFFECTIVENESS
FOR IBL CORTISOL ELISA

DEC 20 2006

Manufacturer: IBL Immuno Biological Laboratories
Flughafenstrasse 52A, D-22335
Hamburg, Germany

Contact Information: **Victor Herbst**
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Device Name / Classification:
The device trade name is the IBL Cortisol ELISA having FDA assigned name: Cortisol (hydrocortisone and hydroxycorticosterone) test system, 21 CFR, **862.1205**, categorized as Class II medical devices for the Clinical Chemistry Panel, as Product Code **CGR.**

Test Principle
Solid phase enzyme-linked immunosorbent assay (ELISA) based on the competition principle. An unknown amount of antigen present in the sample and a fixed amount of enzyme labelled antigen compete for the binding sites of the antibodies coated onto the wells. After incubation the wells are washed to stop the competition reaction. After the substrate reaction the intensity of the developed color is inversely proportional to the amount of the antigen in the sample. Results of samples can be determined directly using the standard curve.

Device Intended Use:
Solid phase enzyme-linked immunosorbent assay for the *in-vitro diagnostic* quantitative determination of free Cortisol in human saliva and of total Cortisol in diluted serum as an aid in the assessment of Cushing Syndrome and Addison's Disease.

Device Performance
All technical data are included in this 510(k) submission. The normal ranges and stability data will be overtaken from the original Cortisol LIA submission No. K052359 (respectively No. K010790) which is manufactured in same way. All single components keep the same, except the substrate system which uses an ordinary TMB (Tetramethylbenzidine) substrate with a given shelf life of 18months by manufacturer. The shelf lifes are therefore as follows:

Stability of kit components at (2 – 8°C) :

Microtiter strips	12 months
Enzyme conjugate.	9 months
Standard A-G	9 months
Kit control 1, 2	9 months
Wash buffer. Concentrate	12 months
ready to use TMB substrate	18 months
TMB Stop solution	36 months

Therefore the complete Kit will have a shelf life of 9 months at 2 – 8°C.

Method comparison

A comparison study was performed using 130 saliva and 1290 serum samples. These samples were tested on the IBL Cortisol ELISA and compared to the Cortisol LIA. The results from measuring the samples in both methods yielded the following correlation:

Method Comparison versus LIA	Saliva	IBL-ELISA = 0.92 x IBL-Luminescence IA + 0.06 µg/dL	r = 0.995;n = 130
	Serum	IBL-ELISA = 1.17 x IBL-Luminescence IA - 2.2 µg/dL	r = 0.997; n = 129

Additionally 33 serum samples from the DGKC (Deutsche Gesllschaft für klinische Chemie, Bonn Germany) quality assessment scheme for hormones which were obtained using a GC/MS method, according to: Siekmann et al., J.Clin.Chem.Clin.Biochem. 20 (1982) 883-892, were used for comparison study to the given GC/MS reference values. The results from measuring the samples yielded the following correlation:

Method Comparison versus GC/MS	Serum	IBL-ELISA = 0.97 x GCMS + 2.3 µg/dL	r = 0.982; n = 33

Interference Studies

The following blood components have been tested in serum and saliva and do not have a significant effect (+/- 20 % of expected) on the test results up to the concentrations stated below:

	Serum	
	Conc.	**Cortisol (µg/dL)**
Hemoglobin	4.0 mg/mL	0.06; 0.33; 0.62
Bilirubin	0.5 mg/mL	0.07; 0.35; 0.63
Triglyceride	30 mg/mL	0.07; 0.40; 0.75
	Saliva	
	Conc.	**Cortisol (µg/dL)**
Thimerosal	0.50 %	0.19; 0.25; 0.34
Blood	0.125 %	0.09; 0.26
NaN_3	0.60 %	0.23; 0.31

The overall performance of the IBL Cortisol ELISA is:

Analytical Specificity (Cross Reactivity)	Substance	Cross Reactivity (%)	Cross-reactivity of other substances tested < 0.01 %
	Prednisolone	29	
	11-Desoxy-Cortisol	16	
	Corticosterone	2.4	
	Cortisone	3.3	
	Prednisone	2.2	
	17α-OH-Progesterone	1.2	
	Desoxy-Corticosterone	0.5	
	6α-Methyl-17α-OH-Progesterone	0.3	

Analytical Sensitivity (Limit of Detection)	0.015 µg/dL	Mean signal (Zero-Standard) - 2SD
Functional Sensitivity	0.060 µg/dL	Mean Conc. < 20 % CV

Precision	Saliva (n = 20)			Serum (1:50 diluted; n = 20)		
	Conc. (µg/dL)	SD (µg/dL)	CV (%)	Conc. (µg/dL)	SD (µg/dL)	CV (%)
Intra-Assay	0.252	0.016	6.4	0.103	0.012	11.8
	0.312	0.024	7.6	0.499	0.053	10.7
	2.927	0.094	3.2	3.421	0.132	3.8
Inter-Assay	0.215	0.020	9.1	0.094	0.010	10.8
	0.864	0.059	6.9	0.394	0.043	10.9
	2.638	0.164	6.2	0.582	0.070	12.0

Linearity	Saliva			Serum		
	Dilution	Meas. (µg/dL)	Rec. (%)	Dilution	Calc. (1:50) (µg/dL)	Rec. (%)
	-	3.035	100	1:50	35.2	100
	1:2	1.259	83	1:100	16.8	96
	1:4	0.635	84	1:200	9.4	107
	1:8	0.340	90	1:400	4.4	101
	1:16	0.184	97	1:800	2.4	111
	1:32	0.108	114	1:1600	1.1	97
	-	0.834	100	1:50	29.6	100
	1:2	0.416	115	1:100	14.4	98
	1:4	0.202	106	1:200	7.5	101
	1:8	0.119	95	1:400	4.4	120
				1:800	2.2	119
	-	0.602	100	1:50	227.2	100
	1:2	0.254	84	1:100	108.9	96
	1:4	0.146	97	1:200	51.4	90
	1:8	0.082	109	1:400	25.8	91
				1:800	13.4	94
				1:1600	6.5	96
				1:3200	3.6	112

Recovery	Saliva				Serum				
	Conc. (µg/dL)	Added (µg/dL)	Meas. (µg/dL)	Rec. (%)	Conc. (µg/dL)	Added (µg/dL)	Meas. (µg/dL)	Expect. (µg/dL)	Rec. (%)
	Saliva 1 (0.25)	0.04	0.30	104	Serum 1 (4.75)	2.0	7.6	6.7	113
		0.08	0.34	105		3.9	8.1	8.7	93
		0.16	0.39	97		7.8	13.7	12.6	109
		0.31	0.61	109		15.6	21.2	20.4	104
		0.63	0.91	104		31.3	38.3	36.0	106
		1.25	1.51	101		62.5	72.0	67.3	107
		2.50	2.19	80		125.0	120.5	129.8	93
	Saliva 2 (0.30)	0.03	0.30	91	Serum 2 (23.0)	2.0	22.1	25.0	89
		0.06	0.37	103		3.9	23.6	26.9	88
		0.13	0.43	102		7.8	27.6	30.8	89
		0.25	0.57	105		15.6	37.6	38.6	97
		0.50	0.93	116		31.3	56.6	54.3	104
		1.00	1.22	94		62.5	83.1	85.5	97
		2.00	2.05	89		125.0	143.6	148.0	97
	Saliva 3 (0.23)	0.03	0.26	97	Serum 3 (31.1)	2.0	32.2	33.1	97
		0.06	0.27	92		3.9	34.6	35.0	99
		0.13	0.39	108		7.8	35.8	38.9	92
		0.25	0.50	103		15.6	44.7	46.7	96
		0.50	0.84	114		31.3	59.2	62.4	95
		1.00	1.48	120		62.5	95.6	93.6	102
		2.00	2.65	119		125.0	146.3	156.1	94

Method Comparison	Saliva	IBL-ELISA = 0.92 x IBL-Luminescence IA + 0.06	r = 0.995; n = 130
	Serum	IBL-ELISA = 1.17 x IBL-Luminescence IA - 2.2	r = 0.997; n = 129
		IBL-ELISA = 0.97 x GCMS + 2.3	r = 0.982; n = 33

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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DEC 2 0 2006

Re: k062626
Trade/Device Name: Cortisol ELISA test kit
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (Hydrocortisone and Hydroxycortisone) test
Regulatory Class: Class II
Product Code: CGR
Dated: November 28, 2006
Received: November 30, 2006

Dear Mr. Herbst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
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Indications for Use

510(k) Number (if known): K062626

Device Name: Cortisol ELISA test kit

Indications For Use:

The IBL Cortisol enzym linked immunosorbent assay is for the *in-vitro-diagnostic* quantitative determination of cortisol in human serum and saliva.

The Cortisol ELISA kit is useful as an aid in the differential diagnosis of Cushing syndrome and Addison's disease.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062626